

AMENDMENTS TO THE CLAIMS

The following listing of claims will replace all prior versions and listings of claims in the application.

LISTING OF CLAIMS

1. (currently amended) A tablet composition free of food effect comprising:
 - a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent; and
 - b) a coating comprising ~~consisting of a polymer component and a non polymer component, wherein the polymer component consists essentially of~~, based on the weight of the coating, ~~from 0 to 30% by weight of polyethylene glycol and~~ from 30 to 80% of a gastroresistant polymer, and ~~the non polymer component comprises, based on the weight of the coating,~~ from 10 to 40% of a hydrophilic silicon dioxide,

wherein the gastroresistant polymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the gastroresistant polymer dissolves, verapamil is released in the intestines without the influence of food intake.

2. (previously presented) A composition according to claim 1, wherein the gastroresistant polymer is selected from the group consisting of uncured poly(meth)acrylic acids, cellulose phthalates, alkylcellulose phthalates, an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, and combinations thereof.

3. (previously presented) A composition according to claim 1, wherein the coating further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

4. (previously presented) A composition according to claim 1, wherein the coating represents from 0.5 to 6% by weight of the core weight.

5. (cancelled)

6. (original) A composition according to claim 1, wherein the core comprises granules compressed together.

7. (cancelled)

8. (cancelled)

9. (currently amended) A tablet composition free of food effect comprising:

- a) a core comprising from 20 to 80% by weight of verapamil and 10 to 80% by weight of a gelling agent; and
- b) a coating comprising ~~consisting of a polymer component and a non polymer component, wherein the polymer component consists essentially of,~~ based on the weight of the coating, ~~from 0 to 30% by weight of polyethylene glycol and~~

from 30 to 80% of uncured poly(meth)acrylic acid polymer, and ~~wherein the non-polymer component comprises~~ from 10 to 40% of a hydrophilic silicon dioxide,

wherein the uncured poly(meth)acrylic acid polymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the poly(meth)acrylic polymer dissolves, verapamil is released in the intestines without the influence of food intake.

10. (previously presented) A composition according to claim 9, wherein the coating further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

11. (currently amended) A tablet composition free of food effect comprising:

- a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent; and
- b) a coating comprising ~~consisting of a polymer component and a non-polymer component, wherein the polymer component consists essentially of~~, based on the weight of the coating, from 5 to 30% by weight of polyethylene glycol and from 30 to 80% of an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, and ~~the non-polymer component comprises~~ from 10 to 40% by weight of a hydrophilic silicon dioxide,

wherein the copolymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the copolymer dissolves, verapamil is released in the intestines without the influence of food intake.

12. (previously presented) The composition according to claim 1, providing effective release of verapamil for a period of at least 8 hours.

13. (previously presented) The composition according to claim 9, providing effective release of verapamil for a period of at least 8 hours.

14. (previously presented) The composition according to claim 11, providing effective release of verapamil for a period of at least 8 hours.

15. – 18. (cancelled)

19. (original) A composition according to claim 1, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carrageen, polyethylene oxide, and combinations thereof.

20. (original) A composition according to claim 9, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose,

carboxymethylcellulose, xanthan gum, carbomer, carragheen, polyethylene oxide, and combinations thereof.

21. (original) A composition according to claim 11, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carragheen, polyethylene oxide, and combinations thereof.

22. (previously presented) A composition according to claim 1, wherein the gastroresistant polymer is soluble at a pH above 5.5.

23. (cancelled)

24. (previously presented) A composition according to claim 11, wherein the copolymer is soluble at a pH above 5.5.

25. (previously presented) A composition according to claim 9, wherein the uncured poly(meth)acrylic acid polymer is soluble at a pH above 5.5.

26. (new) A tablet composition free of food effect comprising:

- a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent;
- b) an intermediate coating; and

c) a coating comprising, based on the weight of the coating, from 30 to 80% of a gastroresistant polymer and from 10 to 40% of a hydrophilic silicon dioxide, wherein the gastroresistant polymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the gastroresistant polymer dissolves, verapamil is released in the intestines without the influence of food intake.

27. (new) A composition according to claim 26, wherein the gastroresistant polymer is selected from the group consisting of uncured poly(meth)acrylic acids, cellulose phthalates, alkylcellulose phthalates, an anionic copolymer of methacrylic acid and acrylic acid ethyl ester, and combinations thereof.

28. (new) A composition according to claim 26, wherein the coating in c) further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

29. (new) A composition according to claim 26, wherein the coating in c) represents from 0.5 to 6% by weight of the core weight.

30. (new) A composition according to claim 26, wherein the intermediate coating comprises hydroxypropylmethylcellulose and polyethylene glycol.

31. (new) A composition according to claim 26, wherein the core comprises granules compressed together.

32. (new) A composition according to claim 26, providing effective release of verapamil for a period of at least 8 hours.

33. (new) A composition according to claim 26, wherein the gastroresistant polymer is soluble at a pH above 5.5.

34. (new) A composition according to claim 26, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carrageen, polyethylene oxide, and combinations thereof.

35. (new) A tablet composition free of food effect comprising:

- a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent;
- b) an intermediate coating; and
- c) a coating comprising, based on the weight of the coating, from 30 to 80% of a uncured poly(meth)acrylic acid polymer and from 10 to 40% of a hydrophilic silicon dioxide,

wherein the polymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the polymer dissolves, verapamil is released in the intestines without the influence of food intake.

36. (new) A composition according to claim 35, wherein the coating in c) further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

37. (new) A composition according to claim 35, wherein the coating in c) represents from 0.5 to 6% by weight of the core weight.

38. (new) A composition according to claim 35, wherein the intermediate coating comprises hydroxypropylmethylcellulose and polyethylene glycol.

39. (new) A composition according to claim 35, wherein the core comprises granules compressed together.

40. (new) A composition according to claim 35, providing effective release of verapamil for a period of at least 8 hours.

41. (new) A composition according to claim 35, wherein the uncured poly(meth)acrylic acid polymer is soluble at a pH above 5.5.

42. A composition according to claim 35, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carragheen, polyethylene oxide, and combinations thereof.

43. (new) A tablet composition free of food effect comprising:

- a) a core comprising from 20 to 80% by weight of verapamil and from 10 to 80% by weight of a gelling agent;
- b) an intermediate coating; and
- c) a coating comprising, based on the weight of the coating, from 30 to 80% of an anionic copolymer of methacrylic acid and acrylic acid ethyl ester and from 10 to 40% by weight of a hydrophilic silicon dioxide,

wherein the copolymer will dissolve in the intestines while withstanding the acidic medium of the stomach and duodenum, and as the copolymer dissolves, verapamil is released in the intestines without the influence of food intake.

44. (new) A composition according to claim 43, wherein the coating in c) further comprises from 5 to 30% by weight based on the total weight of the coating of a plasticizer selected from the group consisting of polyethylene glycol, stearic acid, dibutyl sebacate, propylene glycol, triethyl citrate, and combinations thereof.

45. (new) A composition according to claim 43, wherein the coating in c) represents from 0.5 to 6% by weight of the core weight.

46. (new) A composition according to claim 43, wherein the intermediate coating comprises hydroxypropylmethylcellulose and polyethylene glycol.

47. (new) A composition according to claim 43, wherein the core comprises granules compressed together.

48. (new) A composition according to claim 43, providing effective release of verapamil for a period of at least 8 hours.

49. (new) A composition according to claim 43, wherein the copolymer is soluble at a pH above 5.5.

50. (new) A composition according to claim 43, wherein the gelling agent is selected from the group consisting of hydroxypropylmethylcellulose, hydroxypropylcellulose, carboxymethylcellulose, xanthan gum, carbomer, carrageen, polyethylene oxide, and combinations thereof.